



November 9, 2015

Intercept Pharmaceuticals Reports Third Quarter 2015 Financial Results and Provides Business Update

NEW YORK, Nov. 9, 2015 (GLOBE NEWSWIRE) -- Intercept Pharmaceuticals, Inc. (Nasdaq:ICPT) (Intercept), a clinical stage biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat chronic underserved liver diseases, today reported financial results for the three and nine months ended September 30, 2015 and provided other general business updates. Intercept will hold a conference call and audio webcast today at 8:00 a.m. ET to review this information with conference call details provided below.

Summary of Key Development Programs, Updates and Anticipated Milestones

- Nonalcoholic Steatohepatitis (NASH) Program
 - REGENERATE Phase 3 trial initiated September 2015
 - CONTROL Phase 2 NASH statin trial initiation anticipated in 4Q 2015
- Primary Biliary Cirrhosis (recently renamed Primary Biliary Cholangitis [PBC]) Program
 - PDUFA Date 2/29/2016
 - COBALT Phase 3b confirmatory outcomes trial ongoing
- Primary Sclerosing Cholangitis (PSC) Program
 - AESOP Double-blind phase 2 trial enrolling
 - First clinical trial of OCA in this orphan indication with high unmet medical need
- Biliary Atresia Program
 - Phase 2 trial initiated October 2015
- INT-767 Phase 1 Trial Initiation Anticipated by YE15

Financial Results

Nine Months Ended September 30, 2015 and September 30, 2014

For the nine months ended September 30, 2015 and 2014, Intercept reported a net loss of \$138.1 million and \$248.4 million, respectively. Net loss for the nine month period ended September 30, 2015 included non-cash expenses totaling \$27.6 million, including \$22.0 million of stock-based compensation expense. Net loss for the nine month period ended September 30, 2014 included non-cash expenses totaling \$189.9 million comprised primarily of a non-cash warrant revaluation expense of \$170.8 million and other non-cash expenses of \$19.1 million, including stock-based compensation expense of \$16.5 million.

Research and development (R&D) expenses increased to \$83.7 million for the nine months ended September 30, 2015 from \$56.6 million for the nine months ended September 30, 2014. The \$27.1 million net increase is primarily the result of increases in (i) expenses related to personnel and activities to support our increased development initiatives; (ii) expenses associated with research and discovery initiatives; and (iii) expenses for the INT-767 program.

General and administrative (G&A) expenses increased to \$58.8 million for the nine months ended September 30, 2015 from \$22.7 million for the nine months ended September 30, 2014 primarily as a result of increased corporate and pre-commercial activities and the increase in personnel in support of these initiatives.

Intercept recorded a \$170.8 million non-cash charge related to the periodic revaluation of a warrant liability in the nine months

ended September 30, 2014 primarily attributable to the significant increase in the market price of Intercept's common stock in that period. In connection with equity financings prior to its initial public offering, Intercept had issued warrants that were classified as liabilities and were adjusted to fair value on a quarterly basis with the change in fair value being included in net loss. The amount included in net loss was a non-cash item as Intercept was not required to expend any cash to settle the warrant liability. On April 10, 2014, all warrants outstanding as of March 31, 2014 were exercised on a cashless basis and converted into shares of Intercept common stock. As such, Intercept recorded a final adjustment of approximately \$56 million in non-cash income in the second quarter of 2014 and no further revaluations are necessary.

Three Months Ended September 30, 2015 and September 30, 2014

Intercept reported a net loss of \$50.9 million and \$35.8 million for the three months ended September 30, 2015 and 2014, respectively. The net loss included \$5.7 million and \$5.2 million of non-cash stock-based compensation expenses for the three months ended September 30, 2015 and 2014, respectively. The net loss increase was primarily the result of increases in G&A expenses related to our corporate and pre-commercial activities and the increase in personnel in support of these initiatives.

Cash Position

As of September 30, 2015, Intercept had cash, cash equivalents and investment securities available for sale of approximately \$695.7 million, compared to \$732.2 million as of June 30, 2015.

Intercept projects that adjusted operating expenses for the year ending December 31, 2015 will be below its previous guidance of \$240 million, driven primarily by the timing of hiring of personnel, certain clinical trial and related expenses, market and medical research expenses and manufacturing related purchases for OCA. Adjusted operating expenses in 2015 are planned to support the clinical development program for OCA in PBC, NASH and PSC, the expansion of Intercept's clinical, regulatory, medical affairs and commercial infrastructure in the United States, Europe and other countries such as Canada, increased OCA manufacturing activities, as well as the continued development of INT-767 and other preclinical pipeline programs. The build out of the company's commercial infrastructure is on track with the recent hiring of the U.S. territory business managers and other field personnel in October 2015, and Intercept is continuing its infrastructure expansion in clinical development, regulatory and medical affairs.

Intercept anticipates that stock-based compensation expense will represent the most significant non-cash item that is excluded in adjusted operating expenses as compared to operating expenses under U.S. generally accepted accounting principles, or GAAP. Adjusted operating expense is a financial measure not calculated in accordance with GAAP.

Conference Call on November 9th at 8:00 a.m. ET

Intercept will hold its 2015 third quarter financial results conference call and webcast on Monday, November 9th at 8:00 a.m. ET. The live event will be available on the investor page of the Intercept website at <http://ir.interceptpharma.com> or by calling (855) 232-3919 (toll-free domestic) or (315) 625-6894 (international) five minutes prior to the start time (no passcode is required). A replay of the call will be available on the Intercept website approximately two hours after the completion of the call and will be archived for two weeks.

About Intercept

Intercept is a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat chronic underserved liver diseases. The Company's lead product candidate, obeticholic acid (OCA), is an agonist of the farnesoid X receptor (FXR). OCA is being developed for a variety of chronic liver diseases, including primary biliary cirrhosis, recently renamed primary biliary cholangitis (PBC), nonalcoholic steatohepatitis (NASH), primary sclerosing cholangitis (PSC) and biliary atresia. The FDA has granted OCA breakthrough therapy designation for the treatment of NASH with liver fibrosis and granted OCA fast track designation for the treatment of patients with PBC. OCA has also received orphan drug designation in both the United States and Europe for the treatment of PBC and PSC. Intercept owns worldwide rights to OCA outside of Japan, China and Korea, where it has out-licensed the product candidate to Sumitomo Dainippon Pharma. For more information about Intercept, please visit the Company's website at: www.interceptpharma.com.

Non-GAAP Financial Measures

This press release presents projected adjusted operating expense, which is a non-GAAP measure and should be considered in addition to, but not as a substitute for, operating expense that Intercept prepares and announces in accordance with GAAP. Intercept excludes certain items from adjusted operating expense, such as stock-based compensation and other non-cash items, that management does not believe affect Intercept's basic operations and that do not meet the GAAP definition of unusual or non-recurring items. A reconciliation of projected non-GAAP adjusted operating expense to operating expense calculated in accordance with GAAP is not available on a forward-looking basis without unreasonable effort due to an inability to make accurate projections and estimates related to certain information needed to calculate, for example, future stock-based

compensation expense. Management also uses adjusted operating expense to establish budgets and operational goals and to manage Intercept's business. Other companies may define this measure in different ways. Intercept believes this presentation provides investors and management with supplemental information relating to operating performance and trends that facilitate comparisons between periods and with respect to projected information.

Safe Harbor Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding our financial position, including expected adjusted operating expenses, the activities anticipated to be undertaken by us, our ongoing and anticipated buildout and hiring to support our growing business operations and our strategic directives under the caption "About Intercept." These "forward-looking statements" are based on management's current expectations of future events and are subject to a number of important risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: the initiation, cost, timing, progress and results of our development activities, preclinical studies and clinical trials; the timing of and our ability to obtain and maintain regulatory approval of OCA, INT-767 and any other product candidates we may develop, particularly the possibility that regulatory authorities may require clinical outcomes data (and not just results based on achievement of a surrogate endpoint) as a condition to any marketing approval for OCA, and any related restrictions, limitations, and/or warnings in the label of any approved product candidates; our plans to research, develop and commercialize our product candidates; the election by our collaborators to pursue research, development and commercialization activities; our ability to attract collaborators with development, regulatory and commercialization expertise; our ability to obtain and maintain intellectual property protection for our product candidates; our ability to successfully commercialize our product candidates; the size and growth of the markets for our product candidates and our ability to serve those markets; the rate and degree of market acceptance of any future products; the success of competing drugs that are or become available; regulatory developments in the United States and other countries; the performance of third-party suppliers and manufacturers; our need for and ability to obtain additional financing; our estimates regarding expenses, future revenues and capital requirements and the accuracy thereof; our ability to retain key scientific or management personnel; and other factors discussed under the heading "Risk Factors" contained in our annual report on Form 10-K for the year ended December 31, 2014 filed on March 2, 2015 as well as any updates to these risk factors filed from time to time in our other filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Intercept undertakes no duty to update this information unless required by law.

Intercept Pharmaceuticals, Inc.

Condensed Consolidated Statements of Operations

(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Licensing revenue	\$ 445	\$ 445	\$ 2,336	\$ 1,296
Costs and expenses:				
Research and development	27,487	27,380	83,747	56,593
General and administrative	24,742	9,136	58,854	22,742
Total operating expenses	\$ 52,229	\$ 36,516	\$ 142,601	\$ 79,335
Other income (expense)				
Revaluation of warrants	--	--	--	(170,832)
Other income (expense), net	889	228	2,090	469
Net loss	\$ (50,896)	\$ (35,843)	\$ (138,175)	\$ (248,402)
Net loss attributable to common stockholders	<u>\$ (50,896)</u>	<u>\$ (35,843)</u>	<u>\$ (138,175)</u>	<u>\$ (248,402)</u>
Net loss per common share:				
Basic	\$ (2.10)	\$ (1.69)	\$ (5.89)	\$ (12.07)

Weighted average number of shares of common stock outstanding:

Basic 24,214,913 21,260,303 23,472,026 20,583,146

Condensed Consolidated Balance Sheet Information

(In thousands)

	<u>September 30,</u>	
	<u>2015</u>	<u>2014</u>
Cash, cash equivalents and investment securities	\$ 695,708	\$ 272,806
Total assets	\$ 716,747	\$ 286,021
Deferred revenue, total	\$ 8,463	\$ 10,244
Total liabilities	\$ 38,864	\$ 24,959
Stockholders' equity	\$ 677,883	\$ 261,062

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